

REMARKS

This responds to the Final Office Action mailed on July 23, 2009. This response to the outstanding Office Action is rendered in **appeal brief format**. If the below remarks do not result in allowance of the claims, the Examiner is invited to telephone Applicant's representative, John I. Fischer at 612-371-2134 to discuss whether any agreement can be reached with respect to the claims to avoid an appeal.

Claims 34-42 and 44-46 are amended; no claims are added or canceled. As a result, claims 1, 4-10, 13-31, 33-42, 44-54, and 56-60 are pending in this patent application.

Should the Examiner wish to respond in an Advisory Action with new arguments or new references, Applicant respectfully requests withdrawal of the finality of this Office Action to afford Applicant a full and fair opportunity to respond to the same.

1. REAL PARTY IN INTEREST

The real party in interest of the above-captioned patent application is the assignee, Cardiac Pacemakers, Inc., which is a subsidiary of Boston Scientific Corp.

2. RELATED APPEALS AND INTERFERENCES

There are no other appeals or interferences known to Applicant that will have a bearing on the Board's decision in an appeal of this matter.

3. STATUS OF THE CLAIMS

The present application was filed on September 19, 2003 with claims 1-61. During prosecution claims 2, 3, 11, 12, 32, 43, 55, and 61 were canceled. A Final Office Action (hereinafter "the Final Office Action") was mailed July 23, 2009. Claims 1, 4-10, 13-31, 33-42, 44-54, and 56-60 stand twice-rejected and their rejection provide the basis for the appeal of this matter.

4. STATUS OF AMENDMENTS

Claims 34-42 and 44-46 were amended subsequent to the Final Office Action and prior to the Notice of Appeal to correct issues related to antecedent basis. Applicant respectfully submits that the claims were amended to present the rejected claims in better form for consideration on appeal, that the claims were amended prior to the date of filing a brief, and request that these amendments be entered in view of M.P.E.P. § 1206.

5. SUMMARY OF CLAIMED SUBJECT MATTER

Aspects of the present inventive subject matter include, but are not limited to, methods and systems for information management using an implantable medical device.

INDEPENDENT CLAIM 1

1. A system comprising:
 - a. an information access portal configured to convey patient health data and other information to an authorized, uniquely identified person, the information access portal comprising:
 - an interface to a patient management system, the patient management system configured to store and analyze patient health data; and
 - an interface to an implantable medical device, the implanted medical device configured to sense and transmit patient health data to the patient management system and comprising a proximity recognition system; and
 - b. a recognition module, separate from the implantable medical device, and configured to detect the proximity recognition system in the implantable medical device, uniquely identify the implantable medical device using the proximity recognition system, and authorize access to a person implanted with the implantable medical device to the information access portal.

INDEPENDENT CLAIM 33

33. A system comprising:
 - a. a publicly accessible information access portal configured to convey patient health data and other information to an authorized, uniquely identified person in a

multi-media presentation, the publicly accessible information access portal comprising:

an interface to a patient management system configured to store patient health data and analyze patient health data using at least one clinically derived procedure consistent with a standard of medical care; and

an interface to an implantable medical device configured to sense and transmit patient health data comprising a proximity recognition system; and

- b. a recognition module configured to detect the proximity recognition system in the implantable medical device, uniquely identify the implantable medical device using the proximity recognition system, and authorize access to a person implanted with the implantable medical device to the publicly accessible information access portal.

INDEPENDENT CLAIM 34

34. A method for conveying information to a person comprising the steps of:
- a. detecting, at an electronic recognition module, a proximity recognition system in an implantable medical device implanted in the person;
 - b. granting the person access to a publicly accessible information access portal when the electronic recognition module positively identifies the person as one with a right to access the publicly accessible information access portal;
 - c. conveying information in the form of physiometric data to the identified person through the information access portal; and
 - d. conveying other information to the automatically identified person through the information access portal.

This summary is presented in compliance with the requirements of Title 37 C.F.R. § 41.37(c)(1)(v), mandating a “concise explanation of the subject matter defined in each of the independent claims involved in the appeal ...” Nothing contained in this summary is intended to change the specific language of the claims described, nor is the language of this summary to be construed so as to limit the scope of the claims in any way.

6. GROUND FOR REJECTION TO BE REVIEWED ON APPEAL

I.) Claims 1, 4, 13-14, 16-17, 26-27, 30, 33-36, 44-46, 49, 53, and 54 were rejected under 35 U.S.C. § 102(e) using Leven (U.S. Publication No. 2004/0172290).

7. ARGUMENT

A) The Applicable Law

A.1 Standard of Review

“[T]he examiner bears the initial burden, on review of the prior art or on any other ground, of presenting a prima facie case of unpatentability. If that burden is met, the burden of coming forward with evidence or argument shifts to the applicant.

After evidence or argument is submitted by the applicant in response, patentability is determined on the totality of the record, by a preponderance of evidence with due consideration to persuasiveness of argument.

If examination at the initial stage does not produce a prima facie case of unpatentability, then without more the applicant is entitled to grant of the patent.” *In re Oetiker*, 977 F.2d 1443, 1445 (Fed. Cir. 1992)(citations omitted); *In re Fine*, 837 F.2d 1071, 1074, 5 U.S.P.Q.2d (BNA) 1596, 1598 (Fed. Cir. 1988).

A.2 The Applicable Law under 35 U.S.C. §102

A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987); M.P.E.P § 2131. It is not enough, however, that the prior art reference discloses all the claimed elements in isolation. Rather, “[a]nticipation requires the presence in a single prior reference disclosure of each and every element of the claimed invention, *arranged as in the claim.*” *Lindemann Maschinenfabrik GmbH v. American Hoist & Derrick Co.*, 730 F.2d 1452, 221 USPQ 481, 485 (Fed. Cir. 1984) (citing *Connell v. Sears, Roebuck & Co.*, 722 F.2d 1542, 220 USPQ 193 (Fed. Cir. 1983)) (emphasis added).

A claim in dependent form shall be construed to incorporate by reference all of the limitations of the claim to which it refers. 35 U.S.C. § 112 ¶4. Thus, if a reference does not anticipate a base claim, the reference does not anticipate a claim that depends on the base claim.

B) The References

Leven (U.S. 2004/0172290 A1): relates to a wearable health monitoring device (*see* Leven at Abstract).

C) Discussion of the Rejections

C.1. The Rejection of Claims 1, 4, 13-14, 16-17, 26-27, 30, 33-36, 44-46, 49, 53, and 54 under 35 U.S.C. § 102(e) using Leven.

Leven fails to establish every element of claim 1:

Leven appears to refer to health monitoring system **200** including a wearable health monitoring device **100** that is capable of communicating information to a user computer system **210** or other computer systems, such as a doctor's computer system **220** or a third party computer system **230**. Leven at ¶ 0036 and FIG. 2. Leven also refers to a configuration where the wearable health monitoring device can detect an operative wireless connection link to transmit collected health indicator data to a remote system. *Id.* at ¶ 0041.

First, Applicant cannot find in the cited portions of Leven any disclosure of "an interface to an implantable medical device," as claim 1 recites. Instead, Leven clearly and repeatedly refers to a "wearable health monitoring device **100**." *See, e.g., Id.* at ¶¶ 0014, 0022-0023, and 0037. For example, Leven states "in operation, a health monitoring device **100** can be strapped to one's chest or worn around the neck." ¶ *Id.* at 0037.

As further evidence, Leven goes into great detail of features that may only be found on an external wearable device, such as analog/digital input ports **135**, a power source **125** with rechargeable power supply, a visual power source indicator **145**, and a display screen **170**. *Id.* at ¶¶ 0023, 0024, 0035, and 0055. The display screen appears to be a highly functional display screen that can be used to "display diagnostic information regarding the health monitoring device

100 and can also be used to display ... directions from a health care professional.” *Id.* at ¶ 0035. These features may be unnecessary or at least non-trivial additions to an implantable medical device. Leven contains no teaching of how one may incorporate such features into an implantable device. In fact, the term “implantable” does not even appear in Leven.

Thus, Applicant respectfully submits that the plain meaning of the term “wearable” in conjunction with the description in Leven provides clear evidence that Leven did not contemplate an implantable device when considering the scope and use of a “wearable health monitoring device **100**.”

Moreover, being that there is no implantable medical device in Leven, Applicant respectfully submits that it logically follows that Leven does not disclose “the implanted medical device configured to sense and transmit patient health data to the patient management system and comprising a proximity recognition system,” as claim 1 further recites.

Second, although Applicant contends that Leven fails to disclose an implantable medical device, even if *in argendo*, Leven’s wearable health monitoring device may be construed as including an implantable device, Applicant cannot find in the cited portions of Leven any disclosure of “a recognition module ... configured to ... authorize access to a person implanted with the implantable medical device to the information access portal,” as claim 1 recites.

The Final Office Action relies on paragraphs 0036, 0041, and 0044 of Leven as purportedly supporting the § 102 rejection of this portion of claim 1. Final Office Action at p. 4.

Paragraph 0036 of Leven refers to “providing access to a medical service provider/health professional **225**, such as a doctor, and third party **235**, such as an insurance agency, friends, relatives, or other authorized party.” Clearly, these parties are not ones that have an IMD in them. To wit, they are not “a person implanted with the implantable medical device,” as claim 1 recites. Paragraph 0036 refers to “data received from third parties also can be downloaded and/or accessed from the user’s computer system **210** and/or the health monitoring device **100**.” However, the description of the user’s access to the user’s computer system **210** is devoid of any mention of security or authorization mechanisms.

Paragraph 0041 of Leven refers to “an operative wireless communications link can be detected automatically.” Leven further states that once “a link is detected and a connection is made, the present invention can transmit the collected health indicator data to a remotely located

computer system.” Leven at ¶ 0041. However, there is no disclosure of “a recognition module ... configured to ... authorize access,” as claim 1 recites. In contrast, the detection and connection appear to be made without regard to the user’s identity or authorization. Although Leven further states that “data can be transmitted with a unique identifier corresponding to the user’s **215** identity,” (Leven at ¶ 0041), Applicant respectfully submits that such data is apparently used to tag the collected data with the user’s identity. This tagging allows “software configured to detect particular health indicators ... though comparison with reference models and/or user profiles” and also allows “software can send electronic alerts to the user’s doctor **225**,” as referred to in paragraph 0041 of Leven. Whatever the case, the unique identifier is not used to authorize either the connection or access to the health monitoring system **200**.

Paragraph 0044 begins with “... the invention disclosed herein can be used to transfer health monitor data concerning the user’s **215** vital signs to an authorized third party **235**.” The remainder of paragraph discusses how third parties can access such data. Clearly, these third parties do not include “a person implanted with the implantable medical device,” as recited in claim 1. Moreover, any authorization or security referred to in ¶ 0044 is not to “authorize access to a person implanted with the implantable medical device to the publicly accessible information access portal”, as claimed, but to authorize third parties.

In sum, because Leven does not disclose (1) “an interface to an implantable medical device, the implanted medical device configured to sense and transmit patient health data to the patient management system and comprising a proximity recognition system” or (2) “a recognition module ... configured to ... authorize access to a person implanted with the implantable medical device to the information access portal,” Leven does not establish every element recited in claim 1. Therefore, a proper *prima facie* case of anticipation does not exist. The rejection under § 102(b) in view of Leven is clear error and should be reversed.

Leven fails to establish every element of claim 33:

As discussed above with respect to claim 1, Applicant respectfully submits that Leven fails to disclose “an interface to an implantable medical device” and “a recognition module configured to ... authorize access to a person implanted with the implantable medical device to the publicly accessible information access portal,” as claim 33 recites.

Moreover, Applicant respectfully submits that Leven fails to disclose a “publicly accessible information access portal,” as claim 33 recites. Leven refers to several computers, including a user computer system **210**, a doctor’s computer system **220**, and a third party computer system **230**.

Leven’s “user’s computer system **210**” is not equivalent to Applicant’s claimed “publicly accessible information access portal.” Leven describes the “user’s computer system **210**” in several places, each time conveying that the user’s computer system **210** is personal to the user. For example, Leven states that “the present invention can include a conventional home computer system **210**” (Leven at ¶ 0038), that “the data can be processed, whether in the home of the user **215** on a local computer **210**...” (Leven at ¶ 0041), and refers to the user’s computer system **210** as a “user’s home computer **210**” (Leven at ¶ 0048).

In contrast, for claim interpretation, the PTO must apply to verbiage of the proposed claims the broadest reasonable meaning of the words in their ordinary usage as they would be understood by one of ordinary skill in the art, taking into account whatever enlightenment by way of definitions or otherwise that may be afforded by the written description contained in applicant's specification. M.P.E.P. § 2111 citing *In re Morris*, 127 F.3d 1048, 1054-55, 44 USPQ2d 1023, 1027-28 (Fed. Cir. 1997). Here, the term “publicly accessible” should be construed in contrast to “privately accessible.” A reasonable person would not consider Leven’s user’s home computer as being publicly available or accessible.

In light of this analysis, neither Leven’s “doctor’s computer system **220**” nor “third party computer system **230**” constitute a “publicly accessible information access portal.” As stated in Leven at paragraph 0036, a doctor’s computer system is for the use of “a medical service provider/health professional **225**” and as such, would not be publicly available. In addition, the third party computer system **230** is available to a third party **235**, examples include “an insurance agency, friends, relatives, or other authorized party.” Leven at ¶ 0036. A computer system at an insurance agency is not typically one available for public access. Additionally, computer systems of friends or relatives of the user/patient are arguably at least as private as the user’s computer system **210**. Furthermore, there is no disclosure of the friends or relatives using the user’s computer system **210** or vice versa. Hence, none of the computer systems referred to in Leven are equivalent to Applicant’s “publicly available information portal.”

In sum, because Leven does not disclose (1) “an interface to an implantable medical device” or (2) “a recognition module configured to ... authorize access to a person implanted with the implantable medical device to the publicly accessible information access portal” or (3) a “publicly accessible information access portal,” Leven does not establish every element recited in claim 33. Therefore, a proper *prima facie* case of anticipation does not exist. The rejection under § 102(b) in view of Leven is clear error and should be reversed.

Leven fails to establish every element of claim 34:

As discussed above with respect to claim 1, Applicant respectfully submits that Leven fails to disclose “detecting, at an electronic recognition module, a proximity recognition system in an implantable medical device implanted in the person,” because at least Leven fails to disclose an implantable medical device.

Moreover, as discussed above with respect to claim 1, Leven fails to disclose authorizing access to a person implanted with the implantable medical device. As such, Applicant respectfully submits that Leven also fails to disclose “granting the person access to a publicly accessible information access portal when the electronic recognition module positively identifies the person as one with a right to access the publicly accessible information access portal,” as claim 34 recites because granting the person access relies on the electronic recognition module found in the implantable medical device.

Moreover, as discussed above with respect to claim 33, Leven fails to disclose a “publicly accessible information access portal.” Thus, Applicant respectfully submits that Leven also fails to disclose “granting the person access to a publicly accessible information access portal...” as claim 34 recites.

In sum, because Leven does not disclose (1) “detecting, at an electronic recognition module, a proximity recognition system in an implantable medical device implanted in the person” or (2) “granting the person access to a publicly accessible information access portal when the electronic recognition module positively identifies the person as one with a right to access the publicly accessible information access portal” or (3) a “publicly accessible information access portal,” Leven does not establish every element recited in claim 34.

Therefore, a proper *prima facie* case of anticipation does not exist. The rejection under § 102(b) in view of Leven is clear error and should be reversed.

8. SUMMARY

In sum, because the cited references do not disclose all of the subject matter of claims 1, 33, and 34, in the arrangement as claimed, Applicant respectfully requests reconsideration and withdrawal of the § 102 rejection of these claims. Furthermore, any dependent claims not specifically addressed depend directly or indirectly on independent claims 1 and 34 and accordingly incorporate the limitations of these independent claims. As such, Applicant respectfully requests reconsideration and withdrawal of all bases of rejection of all dependent claims.

CONCLUSION

Applicant respectfully submits that the claims are in condition for allowance, and notification to that effect is earnestly requested. The Examiner is invited to telephone Applicant's representative at (612) 373-6951 to facilitate prosecution of this application.

If necessary, please charge any additional fees or deficiencies, or credit any overpayments to Deposit Account No. 19-0743.

Respectfully submitted,

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Date November 23, 2009

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CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this correspondence is being filed using the USPTO's electronic filing system EFS-Web, and is addressed to: Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on this 23rd day of November, 2009.

Nellie Nuhring

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